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09/890832

August 6, 2001

BOX PCT
Commissioner for Patents
Washington, D.C. 20231

PCT/FR00/00425
-filed February 21, 2000

Re: Application of Patrice VINCENT
A DEVICE FOR INJECTING AN INTRAOCULAR LENS MADE OF FLEXIBLE MATERIAL
Assignee: LABORATOIRE DE CONTACTOLOGIE APPLIQUEE - LCA
Our Ref: Q65738

Dear Sir:

The following documents and fees are submitted herewith in connection with the above application for the purpose of entering the National stage under 35 U.S.C. § 371 and in accordance with Chapter II of the Patent Cooperation Treaty:

☑ an English translation of the International Application.

☑ eight (8) sheets of formal drawings.

☑ an English translation of Article 34 amendments (annexes to the IPER).

☑ a Preliminary Amendment

The Declaration and Power of Attorney and Assignment, will be submitted at a later date.

It is assumed that copies of the International Application, the International Search Report, the International Preliminary Examination Report, and any Articles 19 and 34 amendments as required by § 371(c) will be supplied directly by the International Bureau, but if further copies are needed, the undersigned can easily provide them upon request.

The Government filing fee is calculated as follows:

Total claims	8	-	20	=		x	$18.00	= $.00
Independent claims	1	-	3	=		x	$80.00	= $.00
Base Fee								$860.00
TOTAL FEE								$860.00

A check for the statutory filing fee of $860.00 is attached. You are also directed and authorized to charge or credit any difference or overpayment to Deposit Account No. 19-4880. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.492 which may be required during the entire pendency of the application to Deposit Account No. 19-4880. A duplicate copy of this transmittal letter is attached.

Priority is claimed from February 22, 1999 based on French Application No. 99/02602.

Respectfully submitted,

Robert J. Seas, Jr.
Registration No. 21,092

RJS:rwl

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Patrice VINCENT

Appln. No.: PCT/FR00/00425 Group Art Unit: Not Yet Assigned

Confirmation No.: Not Yet Assigned Examiner: Not Yet Assigned

Filed: August 06, 2001

For: A DEVICE FOR INJECTING AN INTRAOCULAR LENS MADE OF FLEXIBLE MATERIAL

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, please amend the above-identified application as follows:

IN THE CLAIMS:

Please enter the following amended claims:

3/ (Amended) A device according to claim 1, characterized in that the injection end of the piston comprises a plurality of fingers (10a-10b) of hard plastic material capable of flexing towards one another as the piston moves so as to form a cylinder that occupies practically the entire section of the end of the body (1), while simultaneously pushing the lens.

6/ (Amended) A device according to claim 3, characterized in that the single finger or central finger (10a) is extended by a spatula (10c) holding the lens beside the curved face of the body in the thrust space.

7/ (Amended) A device according to claim 1, characterized by using sealing gaskets at the guide head (9) and a stopper closing the end (7) so as to make it possible for the lens to be packaged directly in immersion in a liquid.

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims are amended as follows:

3/ (Amended) A device according to claim 1 ~~or claim 2~~, characterized in that the injection end of the piston comprises a plurality of fingers (10a-10b) of hard plastic material capable of flexing towards one another as the piston moves so as to form a cylinder that occupies practically the entire section of the end of the body (1), while simultaneously pushing the lens.

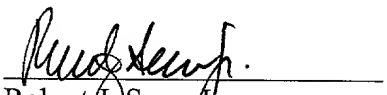
6/ (Amended) A device according to ~~any one of~~ claims ~~3 to 5~~, characterized in that the single finger or central finger (10a) is extended by a spatula (10c) holding the lens beside the curved face of the body in the thrust space.

7/ (Amended) A device according to ~~any one of~~ claims ~~1 to 6~~, characterized by using sealing gaskets at the guide head (9) and a stopper closing the end (7) so as to make it possible for the lens to be packaged directly in immersion in a liquid.

REMARKS

Entry and consideration of this Amendment is respectfully requested.

Respectfully submitted,



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Q65738
Date: August 6, 2001

A DEVICE FOR INJECTING AN INTRAOCULAR LENS MADE OF FLEXIBLE MATERIAL

The present invention relates to a device for use after the natural lens has been removed to inject an intraocular lens (IOL) made of flexible material that has previously been deformed by being compressed, rolled up, or folded.

Most presently known intraocular lens injectors comprise a cylindrical body in which a piston is slidably or screwably mounted: the body is designed to receive a cartridge having a cylindrical endpiece, a loading chamber for receiving the lens to be injected, and a hinged fin; the lens is placed in the chamber and the fin is folded down to close the chamber, thereby deforming the lens, after which the cartridge is placed in the body; once the surgeon has engaged the endpiece in the incision in the eye of a patient, the lens can be injected directly into the capsular bag of the eye being operated on by acting on the piston. Once released, the lens returns to its initial shape.

Other injectors are also known comprising a loading chamber provided with access openings that can be closed by a flap, by a slide, or by being mounted on the endpiece. The lens is deformed either by closing the flap or the slide, or by direct thrust from the piston.

In all those cases, the piston propels the lens into a space of section that tapers progressively, thus contributing to deforming the lens until it reaches the minimum internal section of the endpiece.

Document WO 96/13229 discloses a two-part device comprising forceps and a tubular element each of which needs to be held in one hand. The user takes hold of the lens with the forceps and inserts it into a loading chamber of the tubular element.

The present invention provides an injector which does not have a chamber or loading system with direct access (such as a cartridge, flap, slide, removable

endpiece, ...), and in which the lens is deformed solely by direct thrust from the piston.

The injector of the invention is characterized by a one-piece syringe body having a cylindrical first portion of approximately semicircular section capable of

containing an undeformed lens, an injection endpiece, and an intermediate portion connecting these two portions together and of section that tapers progressively from the cylindrical first portion to the endpiece. The section of the endpiece, which can be circular, oval, or flattened, has dimensions that are adapted to the size of incisions used in the surgical technique of phacoemulsification (presently 3.2 millimeters (mm) or even less as the technique evolves).

In a preferred embodiment of the invention, the injection end of the piston has a plurality of fingers capable of flexing towards one another as the piston moves while simultaneously pushing the lens into the endpiece. By means of this disposition, thrust on the lens is exerted at a plurality of points, thereby stabilizing its orientation. The piston is made as a single piece of hard plastics material, and the fingers are caused to be flexible merely by their shape.

Still in a preferred embodiment of the invention, the lens is delivered in place in the injector, thus relieving the surgeon of the need to load the lens, and constituting a sterile assembly ready for use. Depending on the method of sterilization used, the lens can optionally be packaged dry or immersed in a liquid inside the syringe body: when in a liquid, the assembly is fitted with sealing gaskets for the piston, and with a stopper fitted to the endpiece.

Various embodiments of the injector of the invention are described below as non-limiting examples and with reference to the accompanying drawings, in which:

- Figure 1 is a perspective view of the injector body;
- Figure 2 is a perspective view of the injector piston, with an undeformed lens ready for injection;
- Figure 3 is a perspective view showing the piston mounted in the syringe body, with the lens undeformed, ready for injection;

· Figures 4A to 4E are section views of the body on planes A-A, B-B, C-C, D-D, and E-E at the moment when the lens passes through said planes;

· Figures 5A to 5E are section views of the body on the planes A-A, B-B, C-C, D-D, and E-E at the moments when the ends of the piston pass through said planes;

· Figures 6A to 6E are views similar to Figures 5A to 5E in a second embodiment;

· Figures 7A to 7E are views similar to Figures 5A to 5E in a third embodiment;

· Figures 8A to 8E are views similar to Figures 5A to 5E in a fourth embodiment;

· Figures 9A and 9B are views similar to Figures 2 and 3 with the lens being shown during injection, partially engaged inside the endpiece;

· Figures 10A and 10B are views similar to Figures 2 and 3 with the lens being injected, and partially free at the end of the endpiece;

· Figures 11A and 11B show the same elements and at the same stage as in Figures 10A and 10B, but with the injector turned over so that its chamfer faces downwards; and

· Figure 12 is a perspective view of the piston on its own in a second, undeformed embodiment prior to being mounted in the syringe body.

As shown in the figures, the lens injector of the invention comprises a one-piece syringe body and a piston which are given respective overall references 1 and 2 in the drawings.

The body 1 comprises a portion 3 of semicircular section with a curved face 3a and a plane face 3b, its maximum internal width being substantially equal to that of an intraocular lens 4 when flat (Figure 4A). This portion 3 is followed by a conical portion 5 which connects progressively with a portion 6 that is practically cylindrical. The portion 5 has a curved face 5a and a trapezoidal plane face 5b. The inside diameters

of the portion 6 are such that the lens 4, when folded over, can be received therein, i.e. about 1.6 mm × 2.3 mm (Figure 4E). The portion 6 is terminated by an injection endpiece 7 whose ends can be straight or chamfered and whose outside diameters are about 1.9 mm × 2.6 mm. Depending on the preferred opening direction for the lens, a chamfer, if any, can be oriented towards the curved face side, as in the drawings, or towards the opposite side.

In the embodiment of Figures 1 to 3 and 9 to 12, the piston 2 has a cruciform portion 8 terminated by a cylindrical guide head 9 which can include sealing gaskets and which is of a diameter such as to enable it to travel freely in the portion 3 of the body 1 while guiding the piston. Beyond the head 9, the piston has a multifinger zone which, in the example shown, comprises a central finger 10a and two side fingers 10b. The central finger 10a is extended by a spatula 10a preventing the lens from deforming towards the plane face 3b of the body.

In order to use the injector, the lens is placed in the portion 3 of the body 1 and the piston is mounted in the body until the position shown in Figures 3, 4A, and 5A is reached. The assembly can be sterilized or assembled in sterile manner and is delivered to the surgeon in this form, the surgeon can then remove any stopper and place some lubricating viscoelastic solution in the conical portion 5 of the body 1 for the purpose of improving injection of the lens, should that be part of the surgeon's personal technique.

Using the injector prepared in this way, the surgeon pushes against the piston 2 so the lens 4 is moved into the conical zone 5 of the body: the lens is thus compressed between two diametrically opposite points, thereby causing it to buckle towards the curved face 5a of the body 1 (Figure 4B), since the other face 3b-5b is plane and initially pressed against the lens (Figure 4A),

thus preventing it from buckling in the opposite direction. Thereafter, the lens comes into contact with the curved face 5a so its thinner free edges begin to fold in under towards the plane face 5b (Figure 4C). Simultaneously, the side fingers 10b move towards each other (Figures 4C and then 5C). As the section of the portion 5 tapers, the free edges of the lens 4 slide over the plane face 5b (Figure 4D). The central portion of the lens 4 remains constantly pressed against the curved face 5a, and is therefore stabilized while it is being pushed.

Once they have gone through the conical portion 5 of the body 1, the fingers 10a and 10b meet to constitute a cylinder that occupies practically the entire section of the end 6 of the body 1 (Figure 5E). Meanwhile, the lens 4 is rolled up and likewise occupies this section in full (Figure 4E). When the lens is about to come out, the surgeon inserts the end 7 into the incision with the chamfer facing downwards. Then by continuing to press against the piston 2, the surgeon progressively injects the lens into the eye of the patient, engaging it the capsular bag. Because the lens is resilient, it unfolds and returns to its initial shape.

Once the piston has been pushed fully home, the three fingers project slightly from the end of the body 1 so as to ensure that the lens is released in full.

The embodiment of Figures 6A to 6E is similar to that described above: it differs solely by the fact that the central finger 10a presses continuously against the curved portions 3a and 5a of the body of the injector.

In the embodiment of Figures 7A to 7E, which is similar to the preceding embodiment, the separation planes between the fingers 10a and the fingers 10b instead of being perpendicularly to the plane face of the body, are inclined relative thereto.

In the embodiment of Figures 8A to 8E, the central finger 10a is wedge-shaped. As the side fingers 10b move

towards each other in the conical portion 5, they push the central finger 10a by a wedging action towards the curved face 5a, thus following the movement of the lens.

Naturally, the present invention should not be considered as being limited to the embodiment described and shown, but on the contrary covers all variants thereof.

CLAIMS

1/ A device for injecting an intraocular lens, the device comprising a syringe body (1) in which a piston (2) is mounted, the assembly being suitable for handling in one hand, the device being characterized in that the body (1) is a single piece and comprises a cylindrical portion (3) capable of containing the lens (4) when not deformed, an injection endpiece (6), and a conical intermediate portion (5), and presents no opening, no auxiliary system, such as a cartridge, flap, slide, or removable endpiece, ..., for loading the lens.

2/ A device according to claim 1, characterized in that the syringe body (1) has an internal longitudinal face that is practically plane, the cylindrical portion (3) and the conical intermediate portion (5) having sections that are approximately semicircular.

3/ A device according to claim 1 or claim 2, characterized in that the injection end of the piston comprises a plurality of fingers (10a-10b) of hard plastic material capable of flexing towards one another as the piston moves so as to form a cylinder that occupies practically the entire section of the end of the body (1), while simultaneously pushing the lens.

4/ A device according to claim 3, characterized in that the central finger (10a) bears constantly against the curved inside wall of the syringe body so as to limit the risk of the lens becoming jammed.

5/ A device according to claim 3, characterized in that the central finger (10a) is wedge-shaped and is urged towards the curved wall of the syringe body under the effect of the side fingers (10b) moving towards each other.

6/ A device according to any one of claims 3 to 5, characterized in that the single finger or central finger (10a) is extended by a spatula (10c) holding the lens beside the curved face of the body in the thrust space.

7/ A device according to any one of claims 1 to 6, characterized by using sealing gaskets at the guide head (9) and a stopper closing the end (7) so as to make it possible for the lens to be packaged directly in immersion in a liquid.

8/ A device according to claim 7, characterized by the use of materials that withstand heat, to enable the assembly (device plus lens) to be sterilized in an autoclave.

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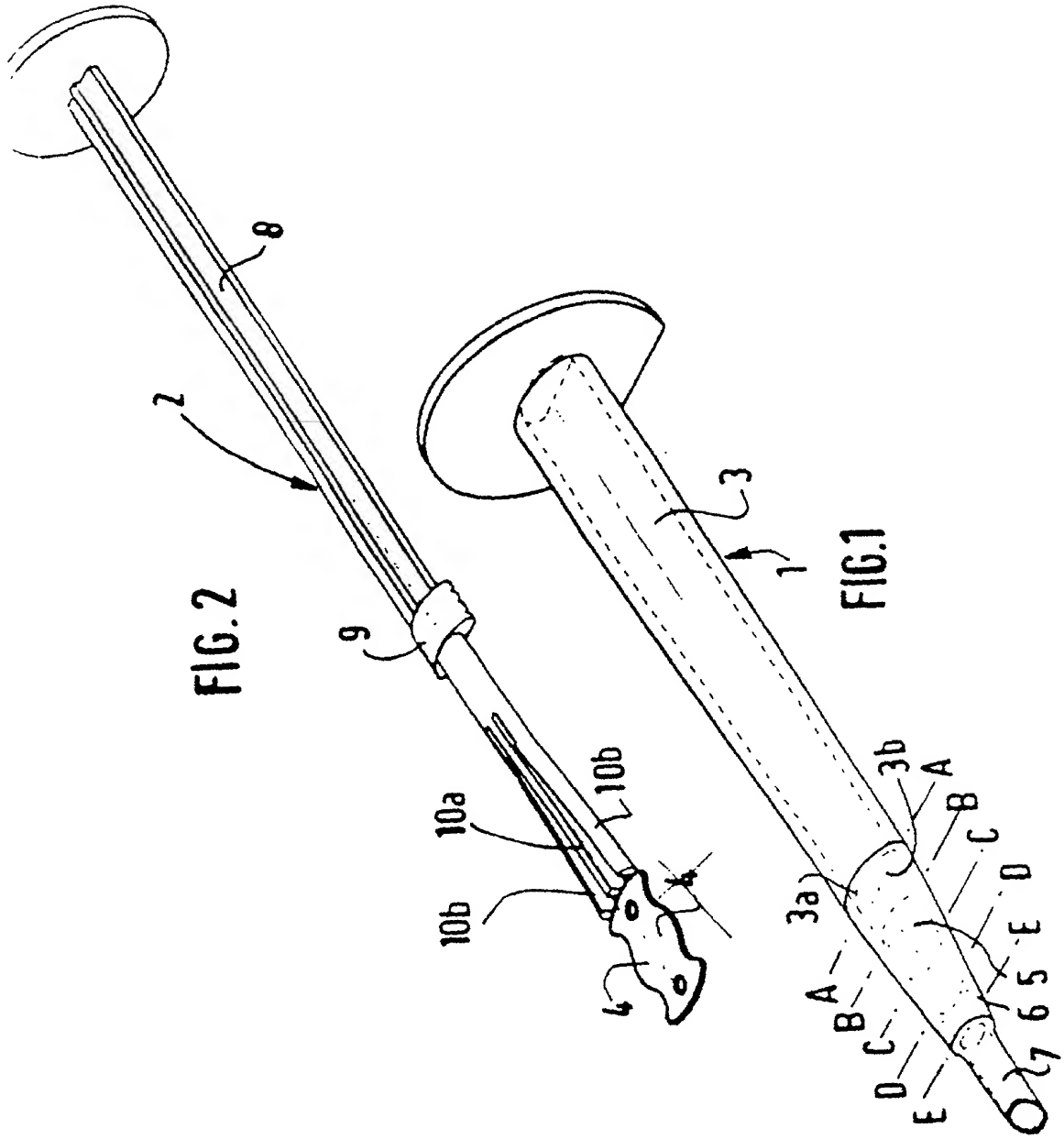

FIG.2

FIG.1

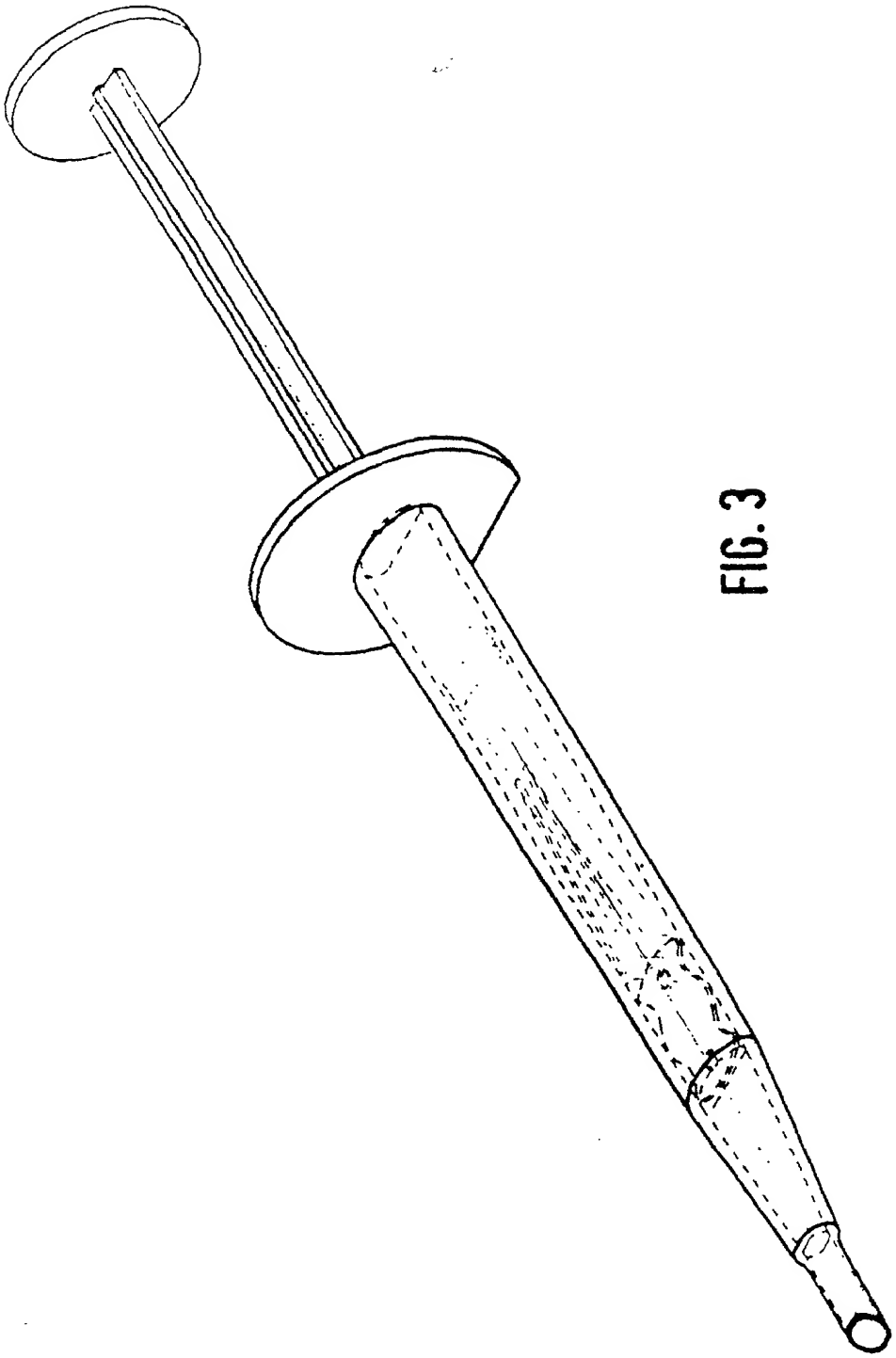

FIG. 3

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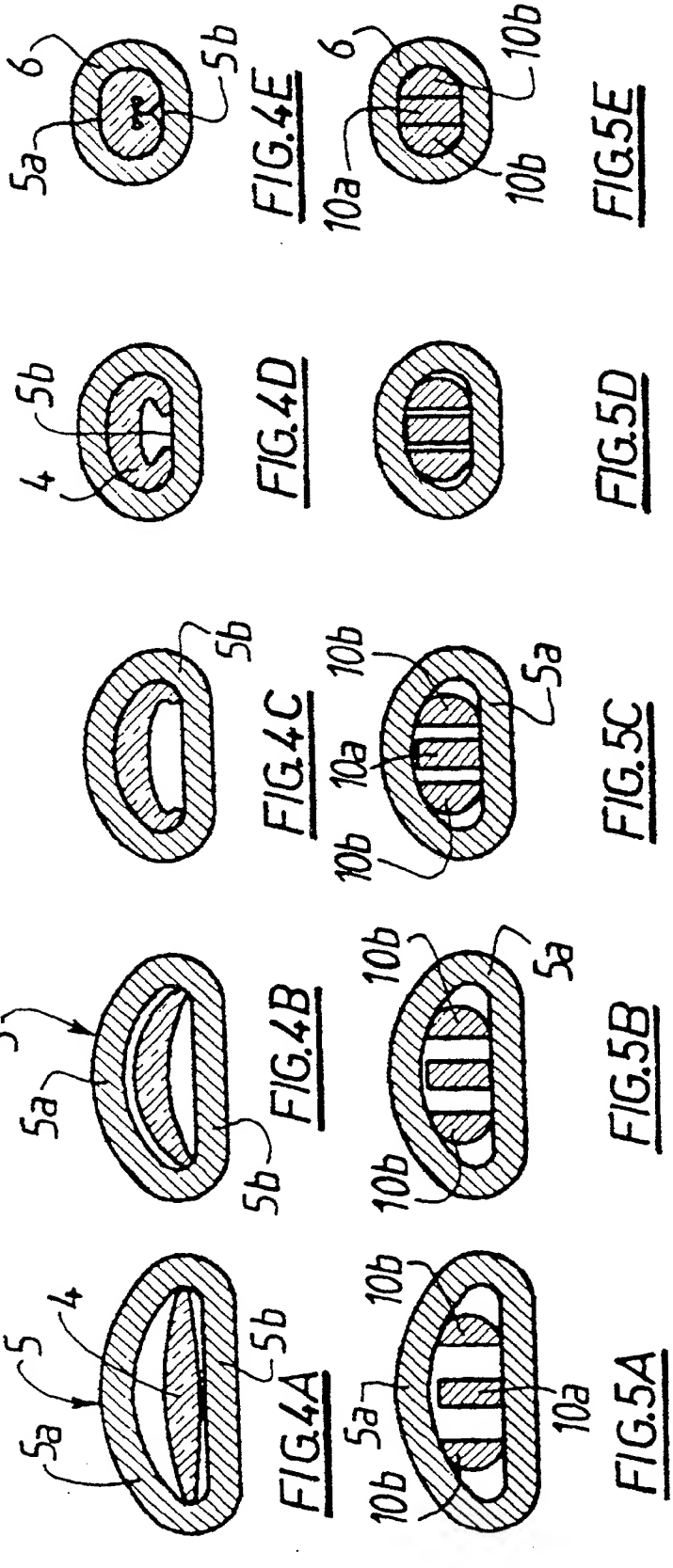

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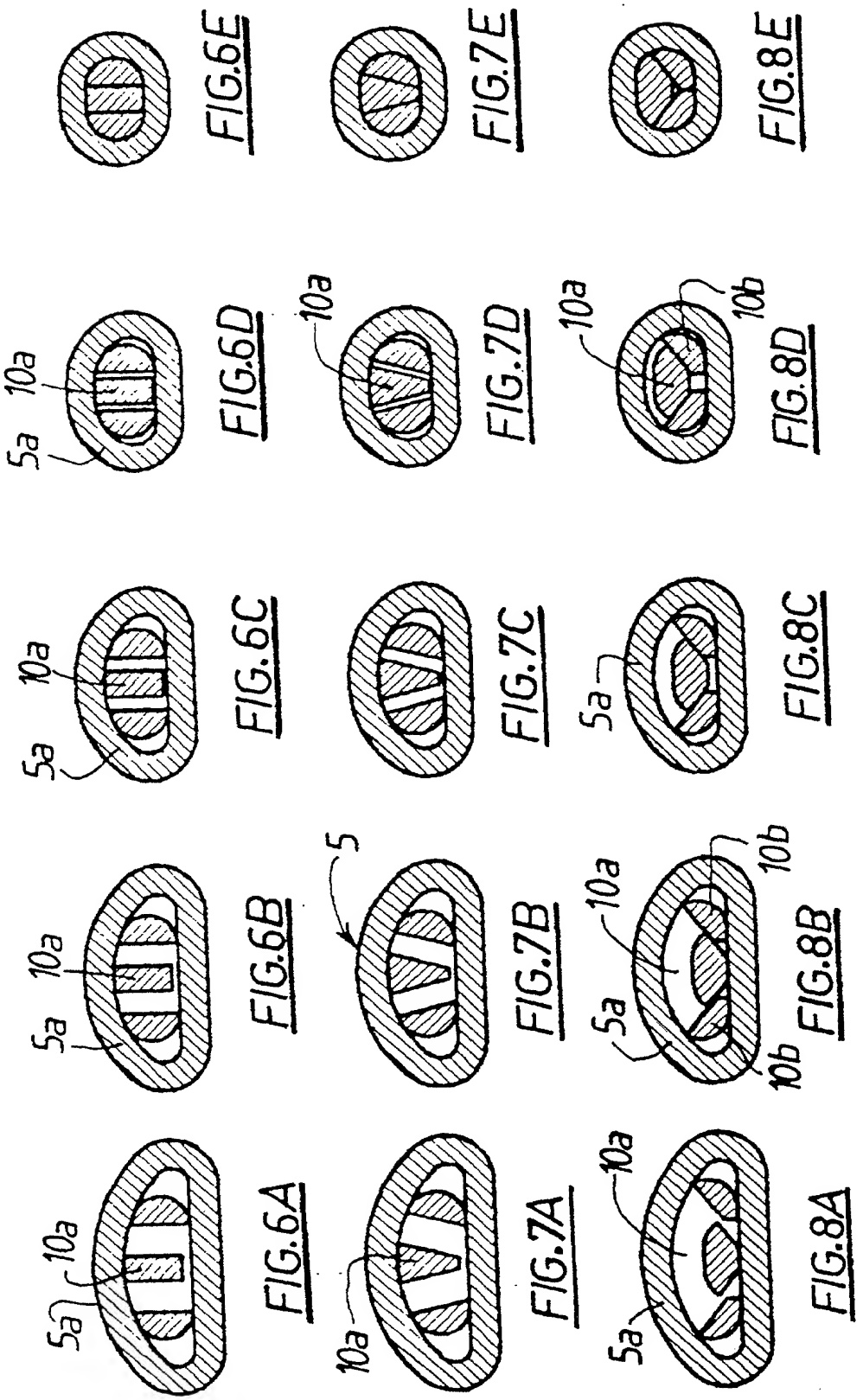

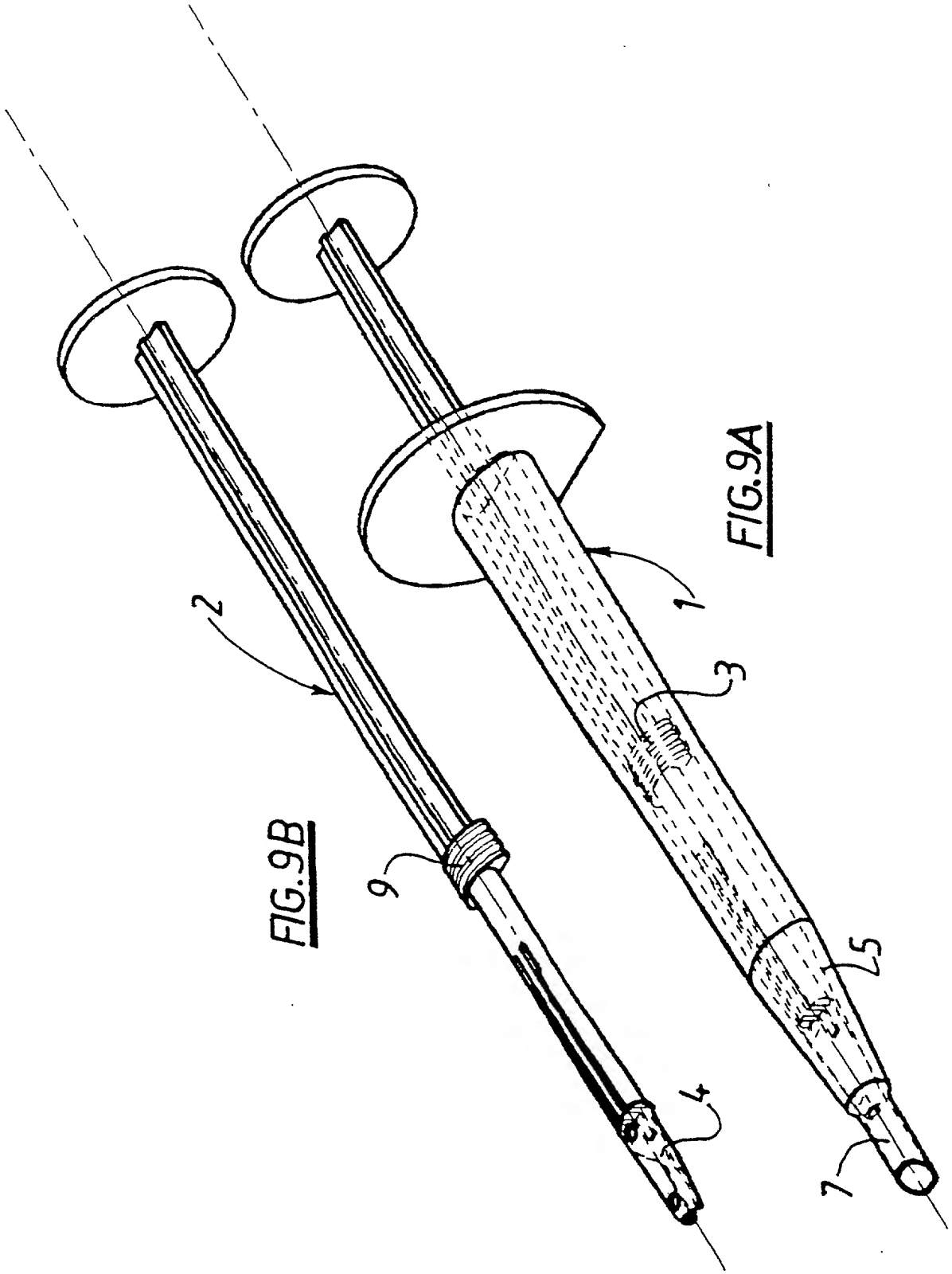

FIG.9B

FIG.9A

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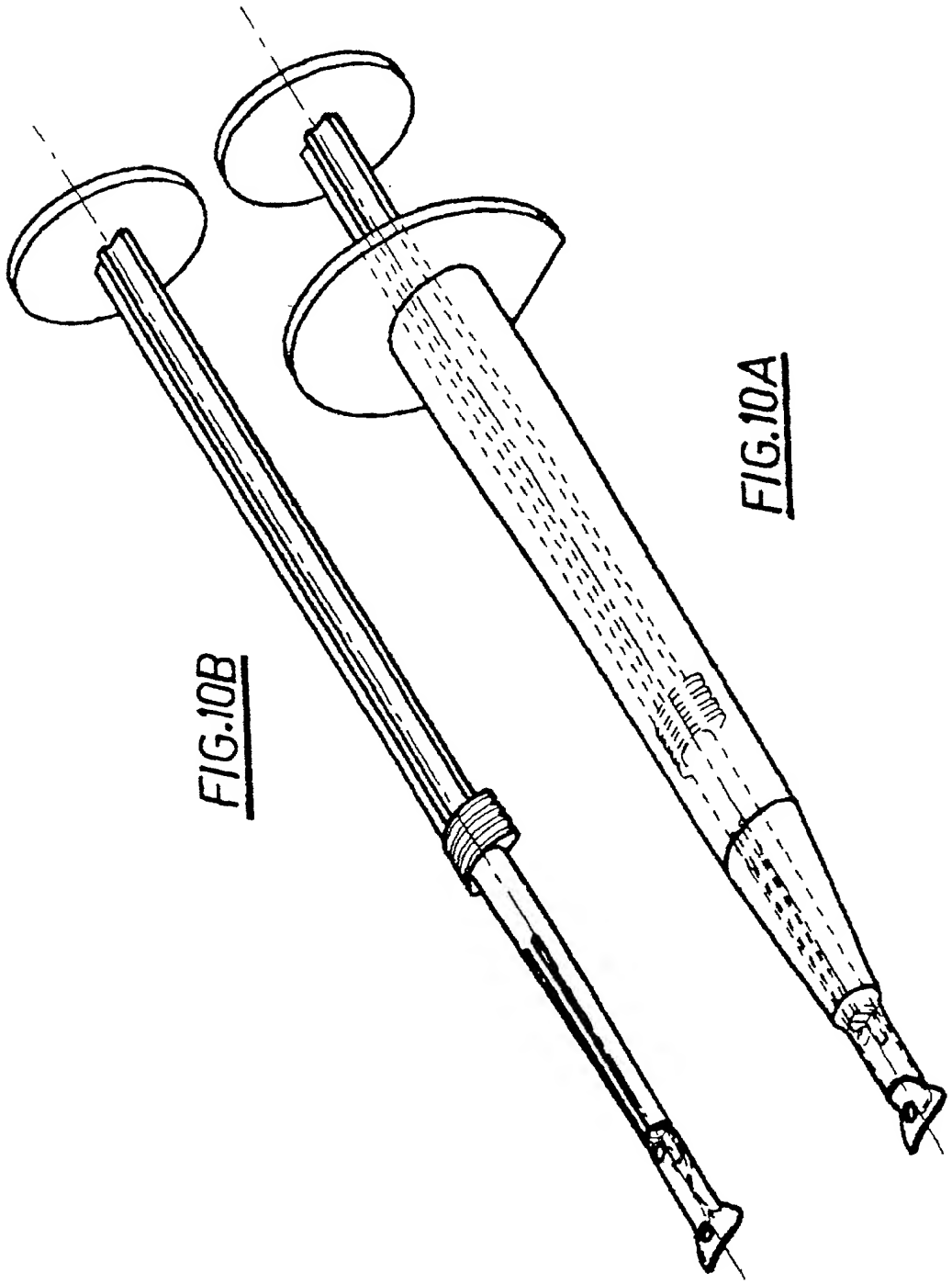

FIG.10A

FIG.10B

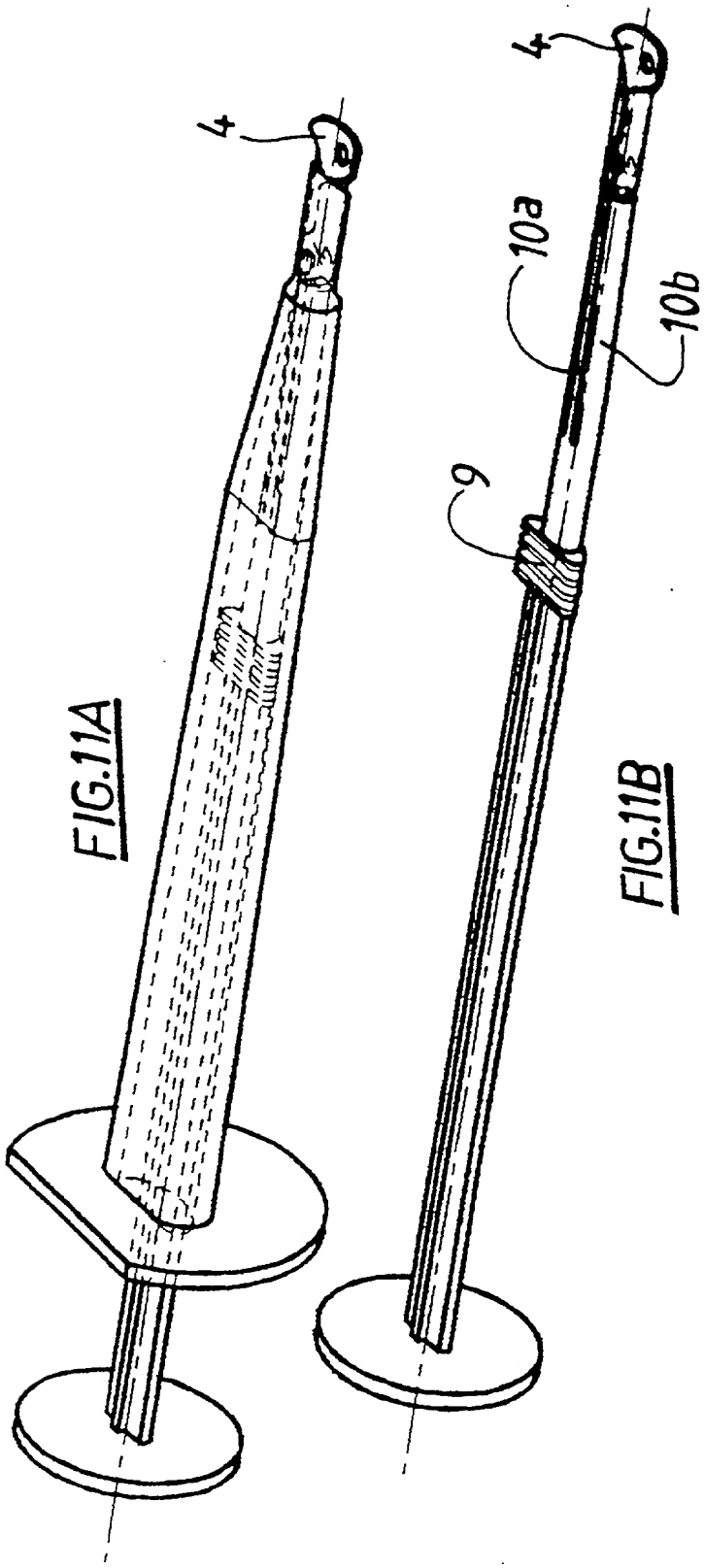

FIG.11A

FIG.11B

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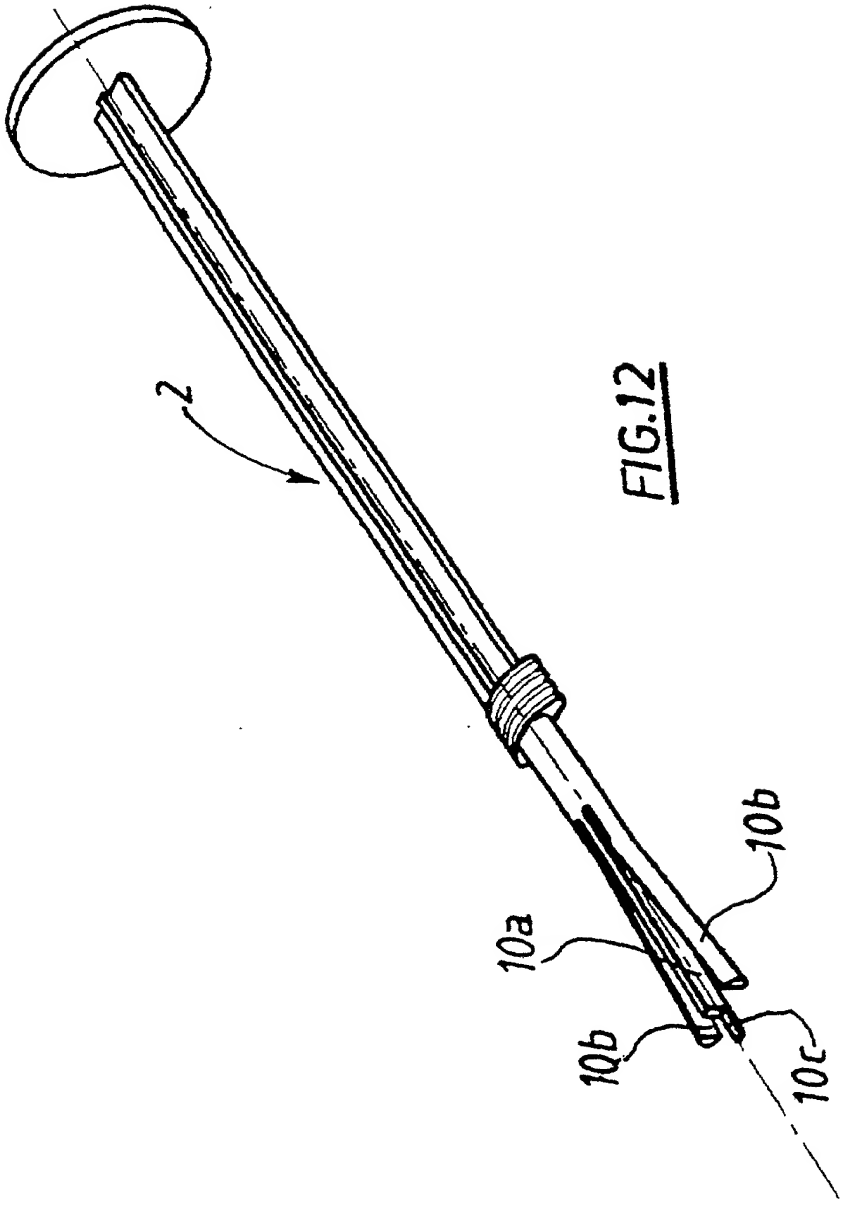

FIG.12

Declaration and Power of Attorney for Patent Application

Déclaration et Pouvoirs pour Demande de Brevet

French Language Declaration

En tant que l'inventeur nommé ci-après, je déclare par le présent acte que:

As a below named inventor, I hereby declare that:

Mon domicile, mon adresse postale et ma nationalité sont ceux figurant ci-dessous à côté de mon nom.

My residence, post office address and citizenship are as stated next to my name.

Je crois être le premier inventeur original et unique (si un seul nom est mentionné ci-dessous), ou l'un des premiers co-inventeurs originaux (si plusieurs noms sont mentionnés ci-dessous) de l'objet revendiqué, pour lequel une demande de brevet a été déposée concernant l'invention intitulée

DISPOSITIF POUR L'INJECTION D'UNE LENTILLE INTRA-OCULAIRE EN MATIERE PLASTIQUE

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

A DEVICE FOR INJECTING AN INTRAOCULAR LENS MADE OF FLEXIBLE MATERIAL

et dont la description est fournie ci-joint à moins que la case suivante n'ait été cochée:

[X] a été déposée le 21.02.2000 sous le numéro de demande des Etats-Unis ou le numéro de demande international PCT PCT/FR00/00425 et modifiée le 19.01.2001 (le cas échéant).

the specification of which is attached hereto unless the following box is checked:

[ ] was filed on February 21, 2000 as United States Application Number or PCT International Application Number PCT/FR00/00425 and was amended on January 19, 2001 (if applicable).

Je déclare par le présent acte avoir passé en revue et compris le contenu de la description ci-dessus, revendications comprises, telles que modifiées par toute modification dont il aura été fait référence ci-dessus.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

Je reconnais devoir divulguer toute information pertinente à la brevetabilité, comme défini dans le Titre 37, § 1.56 du Code fédéral des réglementations.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

French Language Declaration

Je revendique par le présent acte avoir la priorité étrangère, en vertu du Titre 35, § 119(a)-(d) ou § 365(b) du Code des Etats-Unis, sur toute demande étrangère de brevet ou certificat d'inventeur ou, en vertu du Titre 35, § 365(a) du même Code, sur toute demande internationale PCT désignant au moins un pays autre que les Etats-Unis et figurant ci-dessous et, en cochant la case, j'ai aussi indiqué ci-dessous toute demande étrangère de brevet, tout certificat d'inventeur ou toute demande internationale PCT ayant une date de dépôt précédant celle de la demande à propos de laquelle une priorité est revendiquée.

I hereby claim foreign priority under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below, and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Prior foreign application(s) Demande(s) de brevet antérieure(s)		Priority Not Claimed Droit de priorité non revendiqué
99.02602 (Number) (Numéro)	FRANCE (Country) (Pays)	22.02.1999 (Day/Month/Year Filed) (Jour/Mois/Année de dépôt) —
(Number) (Numéro)	(Country) (Pays)	(Day/Month/Year Filed) (Jour/Mois/Année de dépôt) —

☐ Je revendique par le présent acte tout bénéfice, en vertu du Titre 35, § 119(e) du Code des Etats-Unis, de toute demande de brevet provisoire effectuée aux Etats-Unis et figurant ci-dessous.

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

(Application No.) (N° de demande)	(Filing Date) (Date de dépôt)
(Application No.) (N° de demande)	(Filing Date) (Date de dépôt)

☐ Je revendique par le présent acte tout bénéfice, en vertu du Titre 35, § 120 du Code des Etats-Unis, de toute demande de brevet effectuée aux Etats-Unis, ou en vertu du Titre 35, § 365(c) du même Code, de toute demande internationale PCT désignant les Etats-Unis et figurant ci-dessous et, dans la mesure où l'objet de chacune des revendications de cette demande de brevet n'est pas divulgué dans la demande antérieure américaine ou internationale PCT, en vertu des dispositions du premier paragraphe du Titre 35, § 112 du Code des Etats-Unis, je reconnais devoir divulguer toute information pertinente à la brevetabilité, comme défini dans le Titre 37, § 1.56 du Code fédéral des réglementations, dont j'ai pu disposer entre la date de dépôt de la demande antérieure et la date de dépôt de la demande nationale ou internationale PCT de la présente demande:

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

(Application No.) (N° de demande)	(Filing Date) (Date de dépôt)
(Application No.) (N° de demande)	(Filing Date) (Date de dépôt)

(Status)(patented, pending, abandoned)
(Statut)(breveté, en cours d'examen, abandonné)

(Status)(patented, pending, abandoned)
(Statut)(breveté, en cours d'examen, abandonné)

Je déclare par le présent acte que toute déclaration ci-incluse est, à ma connaissance, véridique et que toute déclaration formulée à partir de renseignements ou de suppositions est tenue pour véridique; et de plus, que toutes ces déclarations ont été formulées en sachant que toute fausse déclaration volontaire ou son équivalent est passible d'une amende ou d'une incarcération, ou des deux, en vertu de la Section 1001 du Titre 18 du Code des Etats-Unis, et que de telles déclarations volontairement fausses risquent de compromettre la validité de la demande de brevet ou du brevet délivré à partir de celle-ci.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

French Language Declaration

POUVOIRS: En tant que l'inventeur cité, je désigne par la présente l'(les) avocat(s) et/ou agent(s) suivant(s) pour qu'ils poursuive(nt) la procédure de cette demande de brevet et traite(nt) toute affaire s'y rapportant avec l'Office des brevets et des marques: *(mentionner le nom et le numéro d'enregistrement).*

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: *(list name and registration number)*

31

John H. Mion, Reg. No. 18,879; Donald E. Zinn, Reg. No. 19,046; Thomas J. Macpeak, Reg. No. 19,292; Robert J. Seas, Jr., Reg. No. 21,092; Darryl Mexic, Reg. No. 23,063; Robert V. Sloan, Reg. No. 22,775; Peter D. Olexy, Reg. No. 24,513; J. Frank Osha, Reg. No. 24,625; Waddell A. Biggart, Reg. No. 24,861; Robert G. McMorrow, Reg. No. 19,093; Louis Gubinsky, Reg. No. 24,835; Neil B. Siegel, Reg. No. 25,200; David J. Cushing, Reg. No. 28,703; John R. Inge, Reg. No. 26,916; Joseph J. Ruch, Jr., Reg. No. 26,577; Sheldon I. Landsman, Reg. No. 25,430; Richard C. Turner, Reg. No. 29,710; Howard L. Bernstein, Reg. No. 25,665; Alan J. Kasper, Reg. No. 25,426; Kenneth J. Burchfiel, Reg. No. 31,333; Gordon Kit, Reg. No. 30,764; Susan J. Mack, Reg. No. 30,951; Frank L. Bernstein, Reg. No. 31,484; Mark Boland, Reg. No. 32,197; William H. Mandir, Reg. No. 32,156; Scott M. Daniels, Reg. No. 32,562; Brian W. Hannon, Reg. No. 32,778; Abraham J. Rosner, Reg. No. 33,276; Bruce E. Kramer, Reg. No. 33,725; Paul F. Neils, Reg. No. 33,102; and Bret S. Sylvester, Reg. No. 32,765.

Adresser toute correspondance à:

Send Correspondence to:
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Nom complet de l'unique ou premier inventeur Patrice VINCENT	Full name of sole or first inventor
Signature de l'inventeur Date 13/08/2001	Inventor's signature Date
Domicile 8, rue de Chimay 28130 MEVOISINS / FRANCE FRX	Residence
Nationalité FRANCAISE	Citizenship
Adresse postale Same as domicile	Post Office Address
Nom complet du second co-inventeur, le cas échéant	Full name of second joint inventor, if any
Signature du second inventeur Date	Second inventor's signature Date
Domicile	Residence
Nationalité	Citizenship
Adresse postale	Post Office Address

(Fournir les mêmes renseignements et la signature de tout co-inventeur supplémentaire.)

(Supply similar information and signature for third and subsequent joint inventors.)